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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/672,917 | 09/25/2003 | Casey O'Hara | VT0332-US1 | 9166 |
| 24473 | 7590 | 02/22/2006 | EXAMINER | |
| STEVEN M MITCHELL PACESETTER INC 701 EAST EVELYN AVENUE SUNNYVALE, CA 94086 | | | BERHANU, ETSUB D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3735 | |

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,917

Applicant(s)

O'HARA ET AL.

Examiner

Etsub D. Berhanu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/25/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/08/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19, drawn to an implantable electronic device, classified in class 600, subclass 325.
 - II. Claim 20, drawn to a method of manufacturing an implantable electronic device, classified in class 29, subclass 592.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as using a non-metallic flange.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Steven Mitchell on February 13, 2006 a provisional election was made without traverse to prosecute the invention of Group I. Affirmation of this election must be made by applicant in replying to this Office action. Claim 20 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: elements 86, 88 and 92, Figure 2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: feed through wires 212 and 214, page 14, line 14. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The use of the trademark Tecothane has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. The disclosure is objected to because of the following informalities: Line 12 of page 16 states a “peak-proof” chamber, although it appears that the term “leak-proof” was intended.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 10 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10 and 19 improperly set forth the Markush group; the claim should set forth “the group consisting of,” rather than “a group comprising.”

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 6-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Prutchi et al.'421.

Figure 3 of Prutchi et al.'421 teaches an implantable electronic device comprising: a welded, metal housing 14 (which, because it is made of a corrosion-resistant metal such as stainless steel or titanium, is opaque); an optically-transmissive optical element 20 connected to the housing and defining a leak-proof-sealed, insulating transducer chamber external to the housing (col. 7, lines 17-19); said optical element is transparent (col. 8, lines 49-55) and is made of epoxy, glass, plastics, elastomers or sapphire (col. 7, lines 35-38); electronic cardiac rhythm-sensing circuitry 62 contained within the housing chamber (col. 8, lines 12-23); optical transducers 72, 74 and 76 in the transducer chamber and connected to the circuitry, wherein optical transducers 72 and 74 are LEDs and optical transducer 76 is a photo-detector (col. 9, lines 7-10); optical element 20 is encapsulated in a header element 12 connected to the housing 14 and defining lead apertures having contacts connected to the circuitry (Figure 1, elements 28, 30, 37, 38, 39, 42, 44 and 46).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. Claims 2-5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi et al.'421, as applied to claims 1, 6-17 and 19, further in view of Taylor et al.'513 (US Patent No. 5,871,513).

Prutchi et al.'421 teaches all the elements of the current invention, as discussed in paragraph 8, except for the housing including a closure element hermetically sealing an aperture; the optical element connected to the closure element such that the optical element and closure element together define the transducer chamber; the closure element including a metal shield portion; the optical element joined to the closure element with a leak-proof seal and the optical element hermetically sealed to the closure element.

Taylor et al.'513 teaches a centerless ground feedthrough pin used for connecting an electrical lead or pin to an implantable pulse generator, wherein the feedthrough penetrates the housing but maintains the hermetically sealed environment of the housing; the feedthrough consists of an external metal part into which an insulator solid part (formed of glass, ceramic, or glass and ceramic) is sealed, thus creating a hermetic seal between various components of the implantable medical device (col. 1, lines 25-35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the implantable medical device of Prutchi et al.'421 to include the feedthroughs of Taylor et al.'513, since the feedthroughs of Taylor et al.'513 would hermetically seal the aperture of the housing, the external metal part would partially block electronic interference from passing through the aperture,

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and the optical element joined to the closure element would create a hermetic, leak-proof seal. It is noted that using the feedthroughs of Taylor et al.'513 in the implantable device of Prutchi et al.'421 would create a transducer chamber defined by the feedthroughs and header 20.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

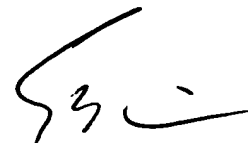
Benz et al. 5,913,881 teaches a hermetically sealed metallic housing for implant including a heading for connecting a stimulation line.

Kinney et al. 4,262,673 teaches a fully implantable medical device comprising a hermetically sealed electric coupling head mounted on a hermetically sealed casing.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571.272.4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ERIC F. WINAKUR
PRIMARY EXAMINER